DOCKET NO. HRT0293

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John H. Stevens, et al.

Serial No.: 10/099,690 Art Unit: 3738

Filed : March 15, 2002 Examiner: D.J. Isabella

For : Method and Apparatus for Thorascoscopic Intracardiac Procedures

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Eugene L. Szczecina, Jr.
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/Eugene L. Szczecina, Jr./
(Signature)

August 23, 2005
(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FOR APPEAL BRIEF

Dear Sir:

Applicant(s) hereby authorize the fee for filing an Appeal Brief in the amount of Five Hundred Dollars ($500.00) to be charged to Deposit Account No. 10-0750/HRT0293/BST in the name of Johnson & Johnson. Any additional fees which may be required in connection herewith may also be charged to Deposit Account No. 10-0750/HRT0293/BST.

This Request is being submitted in triplicate.

Respectfully submitted,

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DATE: August 23, 2005

Docket No. HRT0293

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Applicants	:	John H. Stevens, et al.			
Serial No.	:	10/099,690	Art Unit	:	3738
Filed	:	March 15, 2002	Examiner	:	D.J. Isabella

Title : METHOD AND APPARATUS FOR THORACOSCOPIC INTRACARDIAC PROCEDURES.

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August 23, 2005
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Brian S. Tomko
(Name of applicant, assignee, or Registered Representative)

/Brian S. Tomko/
(Signature)

August 23, 2005
(Date of Signature)

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is filed in triplicate and is in response to the Notice of Appeal, which was received by the U.S. Patent & Trademark Office on June 23, 2005.

Real Party In Interest:

The real party in interest for this patent application is Ethicon, Inc., U.S. Route 22, Somerville, NJ 08876.

Related Appeals and Interferences:

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims:

Claims 1-37, 46 and 65 have been cancelled.

Claims 38-45, 47-64, and 66-73 are pending, have been finally rejected, and are hereby appealed.

Status of Amendments:

No amendments have been filed after the final rejection of December 23, 2004.

Summary of Invention:

In general, the invention contemplates performing ablation on heart tissue with a device (such as that device shown as element 310 in Figure 33 of the specification) introduced through an opening in a patient's chest (thoracoscopically), and performing the ablation while the heart is beating. See, for example, the summary of the invention at page 4 of the specification. Independent claims 38, 47, 69 and 70 define the following different inventions.

Claim 38 claims an invention directed to a method of forming a lesion in heart tissue of a patient to treat atrial fibrillation that consists essentially of: providing an electrophysiological ablating device, such as that device shown as element 310 in Figure 33 of the specification, that comprises at least one electrode (for example, electrode bands 322); creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; passing the electrode through the opening; positioning the electrode adjacent to heart tissue; and ablating the heart tissue with the electrode to create a lesion in the heart tissue while the heart is beating to treat atrial fibrillation. Each of the steps following the providing steps is shown, for example, in Figure 33, and described in the specification at page 38, line 20 through page 42, line 6, among other places.

Claim 47 claims a method of forming a lesion in heart tissue of a patient, comprising: providing a device (for example, element 310 of Figure 33) that has a rigid shaft 312 having a distal end 314 and a proximal end 316, a flexible tip 318 attached to the distal end of the shaft, and at least one ablating element 322 carried on the flexible tip; creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; passing at least a portion of the flexible tip of the device through the opening; positioning the flexible tip of the device adjacent to heart tissue; and ablating the heart tissue with energy delivered from the energy source to create a lesion in the heart tissue while the heart is beating. Each of the steps following the providing steps is shown, for example, in Figure 33, and described in the specification at page 38, line 20 through page 42, line 6, among other places.

Claim 69 claims a method of forming a lesion in heart tissue of a patient, comprising: providing a device 310 comprising a rigid shaft 312 having a distal end 314 and a proximal end 316, a flexible tip 318 attached to the distal end of the shaft, and at least one ablating element 322 carried on the flexible tip; creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity; passing the distal end of the device through the opening; positioning the distal end of the device adjacent to heart tissue; and delivering energy via the device to the distal end of the device to create a lesion in the heart tissue while the heart is beating. Each of the steps following the providing steps is shown, for example, in Figure 33, and described in the specification at page 38, line 20 through page 42, line 6, among other places.

Claim 70 claims a method of forming a lesion in heart tissue of a patient, comprising: providing a device 310 comprising a rigid shaft 312 having a distal end 314 and a proximal end 316, a flexible tip 318 attached to the distal end of the shaft, and at least one ablating element 322 carried on the flexible tip; creating an opening in a patient's chest without retracting the sternum, the opening passing through the chest wall and into the patient's thoracic cavity; passing at least the distal end of the device through the opening; positioning the distal end of the device adjacent to heart tissue; and delivering energy via the device to the distal end of the device to create a lesion in the heart tissue while the heart is beating.

Each of the steps following the providing steps is shown, for example, in Figure 33, and described in the specification at page 38, line 20 through page 42, line 6, among other places.

Issues:

Whether the final rejection of claims 38-45, 47-64, and 66-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,161,543 should be reversed.

Grouping of Claims:

Claims 38-45, 47-64, and 66-73 stand or fall together.

Argument:

Obvious-Type Double Patenting Rejections

As a preliminary matter, claims 38-45, 47-64, and 66-73 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of three different references: (1) claims 1-11 of U.S. Patent No. **6,161,543**; (2) claims 1-6 and 9 of U.S. Patent No. **5,829,447**; and (3) claims 38-44 and 57-69 of copending U.S. Patent Application No. **10/427,438**. Appellants appeal only the first rejection; i.e., the obviousness-type double patenting rejection in view of claims 1-11 of U.S. Patent No. 6,161,543. As to the other two obviousness-type double patenting rejections, Appellants submit a terminal disclaimer for each reference that moots the rejections.

The sole remaining issue relates to claims 38-45, 47-64, and 66-73, which stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,161,543 ("the Cox patent").

Obviousness-type double patenting requires rejection of an application claim when the ***claimed*** subject matter is not patentably distinct from the ***claims*** of the patent in question. See MPEP §804 II.B.1 (page 800-22 (9th ed. rev. 2)). In this case, the claimed subject matter of the application is patentably distinct from the claims of the Cox patent. First, the claims of

the Cox patent do not describe the inventions claimed in independent claims 38, 47, 69 and 70 of the subject application. The sole independent claim of Cox, claim 1, reads as follows:

> A method of ablating epicardial tissue around the pulmonary veins, comprising the steps of:
> providing at least one ablation device having at least one ablating element;
> introducing the ablation device into the patient's chest;
> positioning the ablating element in contact with a location ***on an epicardial surface of the heart***; and
> ablating tissue to form a lesion ***around the pulmonary veins*** with the at least one ablating element positioned at the location on the epicardial surface to form at least part of the lesion around the pulmonary veins.

Note that claim 1 of Cox requires forming a lesion ***around the pulmonary veins*** with the at least one ablating element ***positioned at the location on the epicardial surface*** to form at least part of the lesion around the pulmonary veins. As is shown below, none of the pending claims of the subject application claims (claims 38, 47, 69 and 70) ablating an epicardial surface. Nor do the independent claims claim ablating around the pulmonary veins. Claim 38 is presented below.

> 38. A method of forming a lesion in heart tissue of a patient to treat atrial fibrillation, consisting essentially of:
> providing an electrophysiological ablating device comprising at least one electrode;
> creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity;
> passing the electrode through the opening;
> positioning the electrode adjacent to heart tissue; and
> ablating the heart tissue with the electrode to create a lesion in the heart tissue while the heart is beating to treat atrial fibrillation.

Further, claim 38 (and claims 47, 69 and 70) includes, among other differences, a step that the Cox patent does not claim: "ablating the heart tissue with the electrode to create a lesion in the heart tissue ***while the heart is beating to treat atrial fibrillation***." Not one of the claims 1-11 of the Cox patent describe this step. As a result, it is apparent that the claims of the Cox patent do not anticipate the independent claims of the subject application as they do not claim the same subject matter.

Further the claims of the Cox patent do not render the independent claims of the subject application obvious. The claims of the Cox patent do not describe the step of ablating the heart tissue while the heart is beating to treat atrial fibrillation. The Examiner has, for each of the pending claims, pointed out in the specification of Cox where the elements of the pending claims find support. See pages 2-3 of the December 23, 2004 Office Action. It is well-settled, however, that "[w]hen considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, ***the disclosure of the patent may not be used as prior art***." MPEP §804 II.B.1 (page 800-22 second column); General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1280-81 (Fed. Cir. 1992). As a result, reliance on the specification of the Cox patent is not appropriate. Appellants submit that without referring to the specification of the Cox patent, the Examiner can not support the obviousness rejection as one skilled in the art would not find such differences obvious.

Appellants point out that the double patenting obviousness-type patenting rejection over the Cox patent was first presented by the Examiner in an Office Action dated December 18, 2002. Appellants responded to that Office Action on May 16, 2003, with arguments very similar to those presented herein. The Examiner apparently agreed with Appellants arguments at that time, as a Notice of Allowance was issued thereafter on August 11, 2003. Appellants filed an RCE thereafter to have additional prior art considered by the Examiner, and thereafter the same rejection was presented.

Conclusion:

For the reasons discussed above, Appellants maintain that the Examiner's final rejection of claims 38-45, 47-64, and 66-73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,161,543 should be reversed.

Respectfully submitted,

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Dated: August 22, 2005

APPENDIX

1-37. (Cancelled)

38. (Amended) A method of forming a lesion in heart tissue of a patient to treat atrial fibrillation, consisting essentially of:

providing an electrophysiological ablating device comprising at least one electrode;

creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity;

passing the electrode through the opening;

positioning the electrode adjacent to heart tissue; and

ablating the heart tissue with the electrode to create a lesion in the heart tissue while the heart is beating to treat atrial fibrillation.

39. (Original) The method of claim 38, comprising the steps of:

creating a second opening in the wall of the patient's heart, the second opening passing through the wall of the heart and into an interior chamber of the heart;

positioning the electrode through the second opening and within an interior chamber of the heart prior to the step of ablating the heart tissue with the electrode.

40. (Original) The method of claim 39, wherein the step of positioning the electrode within a chamber of the patient's heart comprises the steps of:

introducing a tubular access device into the second opening, the access device having an inner lumen and a distal end;

inserting the electrophysiological ablation device through the inner lumen of the tubular access device such that the electrode extends beyond the distal end of the access device and within an interior chamber of the heart.

41. (Original) The method of claim 38, wherein the opening is created intercostally and the electrophysiological ablation device is introduced through the intercostal space.

42. (Original) The method of claim 41, wherein the opening is a small percutaneous incision in the space between the ribs.

43. (Original) The method of claim 38, wherein the opening is created without retracting the sternum.

44. (Amended) The method of claim 38, wherein the opening is created without retracting the ribs.

45. (Original) The method of claim 38, wherein the step of ablating the heart tissue comprises the step of applying radiofrequency energy to create the lesion in the heart tissue.

46. (Cancelled)

47. (Amended) A method of forming a lesion in heart tissue of a patient, comprising:

providing a device comprising a rigid shaft having a distal end and a proximal end, a flexible tip attached to the distal end of the shaft, and at least one ablating element carried on the flexible tip;

creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity;

passing at least a portion of the flexible tip of the device through the opening;

positioning the flexible tip of the device adjacent to heart tissue; and

ablating the heart tissue with energy delivered from the energy source to create a lesion in the heart tissue while the heart is beating.

48. (Amended) The method of claim 47, comprising the steps of:

creating a second opening in the wall of the patient's heart, the second opening passing through the wall of the heart and into an interior chamber of the heart;

positioning at least a portion of the flexible tip of the device through the second opening and within an interior chamber of the heart prior to the ablating step.

49. (Amended) The method of claim 48, wherein the step of positioning the at least a portion of the flexible tip of the device within a chamber of the patient's heart comprises the steps of:

introducing a tubular access device into the second opening, the access device having an inner lumen and a distal end;

inserting the device through the inner lumen of the tubular access device such that the at least one ablating element extends beyond the distal end of the access device and within an interior chamber of the heart.

50. (Previously Presented) The method of claim 47, wherein the opening is created intercostally and the device is introduced through the intercostal space.

51. (Previously Presented) The method of claim 47, wherein the opening is a small percutaneous incision in the space between the ribs.

52. (Previously Presented) The method of claim 47, wherein the opening is created without retracting the sternum.

53. (Previously Presented) The method of claim 47, wherein the opening is created without retracting the ribs.

54. (Previously Presented) The method of claim 47, wherein the step of ablating the heart tissue comprises the step of applying radiofrequency energy to create the lesion in the heart tissue.

55. (Previously Presented) The method of claim 47, wherein the energy source is radiofrequency energy.

56. (Previously Presented) The method of claim 47, wherein the energy source is a laser.

57. (Amended) The method of claim 47, wherein the device has a first configuration and a second configuration, and comprising the step of actuating the device to configure at least the distal end of the device in the second configuration prior to the step of ablating.

58. (Amended) The method of claim 57, wherein the actuating step causes at least the distal end of the device to deflect.

59. (Previously Presented) The method of claim 57, wherein the actuating step creates a compressive force.

60. (Previously Presented) The method of claim 57, comprising the step of actuating the device to create a compressive force.

61. (Amended) The method of claim 47, wherein the step of ablating comprises creating ablation lines in the myocardium to create a directed conduction pathway.

62. (Amended) The method of claim 47, wherein the step of ablating comprises creating at least one ablation line of the Cox maze procedure.

63. (Amended) The method of claim 47, wherein the step of ablating comprises creating ablation lines in the myocardium to treat atrial fibrillation.

64. (Amended) The method of claim 63, wherein the ablation lines are for creating a directed conduction pathway is between the sinoatrial node and the atrioventricular node.

65. (Cancelled)

66. (Previously Presented) The method of claim 47, wherein the device comprises at least one electrode and wherein the positioning step positions the at least one electrode against the heart tissue.

67. (Previously Presented) The method of claim 47, wherein the device has a length of approximately 20 to 30 cm.

68. (Previously Presented) The method of claim 47, wherein the device has a length of at least 20 cm.

69. (Amended) A method of forming a lesion in heart tissue of a patient, comprising:

providing a device comprising a rigid shaft having a distal end and a proximal end, a flexible tip attached to the distal end of the shaft, and at least one ablating element carried on the flexible tip;

creating an opening in a patient's chest, the opening passing through the chest wall and into the patient's thoracic cavity;

passing the distal end of the device through the opening;

positioning the distal end of the device adjacent to heart tissue; and

delivering energy via the device to the distal end of the device to create a lesion in the heart tissue while the heart is beating.

70. (Amended) A method of forming a lesion in heart tissue of a patient, comprising:

providing a device comprising a rigid shaft having a distal end and a proximal end, a flexible tip attached to the distal end of the shaft, and at least one ablating element carried on the flexible tip;;

creating an opening in a patient's chest without retracting the sternum, the opening passing through the chest wall and into the patient's thoracic cavity;

passing at least the distal end of the device through the opening;

positioning the distal end of the device adjacent to heart tissue; and

delivering energy via the device to the distal end of the device to create a lesion in the heart tissue while the heart is beating.

71. (Previously Presented) The method of claim 70, wherein the opening is created without retracting the ribs.

72. (Previously Presented) The method of claim 70, wherein the opening is created intercostally.

73. (Previously Presented) The method of claim 72, wherein the opening is a small percutaneous incision in the space between the ribs.